MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

October 1, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Docket 99N-2874 -- Development of Guidance Documents for Medical Devices Regulated by the Center for Biologics Evaluation and Research

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment in advance of the November 15 public meeting and teleconference on the development of guidance documents for medical devices regulated by the Center for Biologics Evaluation and Research (CBER). MDMA represents 130 independent manufacturers of medical technology, including companies whose products are regulated by CBER. As such, we take a keen interest in the efficiency and effectiveness of CBER in reviewing medical product applications and protecting the public health.

MDMA is pleased that CBER has heard industry's concerns and complaints with CBER's processes for reviewing device applications. We are disappointed, however, that CBER has chosen to forge ahead with its "Device Action Plan" without seriously considering the common-sense recommendations that MDMA has made at CBER's public meetings and in writing.

As you may recall, in our December 1998 comments to the docket following that month's Device Action Plan Workshop, MDMA encouraged CBER "to consider transferring its management responsibilities for reviewing device submissions to CDRH (the Center for Devices and Radiological Health)." MDMA argued that "this action, combined with the transfer of appropriate resources, would speed review of these devices and allow CBER to sharpen its focus on its core missions of regulating biological products and protecting the nation's blood supply."

To our knowledge, CBER never seriously considered this proposal. The only possible acknowledgement we can find of our recommendation is in the preamble to the Device Action Plan, where CBER writes that "CBER has developed specific expertise in blood, blood products and cellular therapies and the integral association of certain medical devices with those biological products supports the regulation of those devices by CBER."

Granted, CBER has certain expertise with these products that require CBER's involvement in their regulation, as MDMA acknowledged in our December 1998 comments. However, we do not understand how transferring management responsibilities for device review to CDRH, while still consulting with CDRH on particular technical and scientific aspects during the process, would be detrimental to the public health or the safety of the nation's blood supply.

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Furthermore, we cannot comprehend how CBER's duplication and replication of many of CDRH's reengineering efforts can be considered an effective use of FDA's limited resources.

Clearly, CDRH is much more adept than CBER at managing the review process. According to published reports, the average CBER review time for 510(k) premarket submissions in calendar year 1997 was nearly 360 days. In contrast the average CDRH review time for 510(k)s in fiscal year 1997 was 130 days. Furthermore, in this fiscal year, only nine of the 25 510(k)s received by CBER's Division of Blood Applications had "first actions" during the first ninety days following receipt.

CBER received 53,341 submissions in fiscal year 1997, according to the center's annual report. Of these submissions, only 74 were 510(k) submissions, premarket approval (PMA) applications, or PMA supplements. Since device submissions and applications are such a miniscule part of CBER's workload, MDMA cannot understand CBER's reluctance to allow CDRH to manage their review in consultation with CBER.

Finally, if progress on the Device Action Plan is a gauge of CBER's commitment to improving its device review processes, then we may have even more reason to be concerned with the direction in which CBER is heading. Perhaps CBER has accomplished many of the early-stage goals of the Device Action Plan, but we have been unable to find any publicly available information on most of the action items set forth in the Plan. We hope that CBER will update the public at the November 15 meeting on CBER's progress toward achieving the following goals and meeting the following timetables, pulled in rough chronological order from the Device Action Plan:

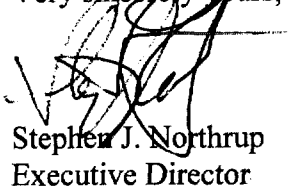
a. Develop a CBER device training plan in coordination with CDRH training initiatives and workshops for FDAMA policies and procedures (May 2, 1999).
b. Assign CBER staff liaisons to appropriate CDRH reengineering work groups (May 2, 1999).
c. Analyze application processing for delays and implement improved processing (June 1, 1999). Develop business practices model and initiate improved practices, including streamlining procedures (October 1, 1999). Clarify expectations of reviewers, project managers, committee chairs and managers within managed review process harmonized with other applications (August 1, 1999). Develop training plan for all staff (June 1, 1999). Hold staff go-away to communicate goals and develop participation (July 1, 1999).
d. Define problem by analyzing issues of backlog, numbers of review cycles, review time, and resource staffing for FY 96-98 (June 1). Determine workload distribution, complexity, scientific staffing and operating dollar needs (July 1, 1999). Develop review expectations for FY 99, FY 2000, and FY 2001 using FDAMA criteria (August 1, 1999).
e. Assign a CBER/CDRH task force to review, revise and update the intercenter agreement (June 30, 1999).

f. Identify and initiate needed organization changes (July 1, 1999).
g. The ORA/CBER/CDRH/CDER GMP group will complete their document clarifying applicability of stability/ and sterility requirements to CBER regulated IVDs (September 15, 1999).
h. A working group from the Team Biologics Operations group (which includes CBER), with additional staff from CDER and CDRH, chaired by ORA/Office of Enforcement, will:
    1. Determine whether there are licensed biological products where we could apply device methods and therefore lighten the inspection load (e.g., tines, pre-filled syringes, and injectors) (September 30, 1999).
    2. Determine whether any differences from CDRH policies are justified and beneficial (September 30, 1999).
    3. Make recommendations to the full Operations Group (September 30, 1999).

FDA officials maintain that the agency does not have enough resources to carry out its core missions, yet the FDA and CBER continue to spend thousands of hours of staff time and untold dollars pressing forward with this redundant Device Action Plan. The common-sense solution would be to give CDRH management responsibility for the handful of device types currently reviewed by CBER, while involving CBER staff in certain aspects of the review process where appropriate. This would actually contribute to the public health by speeding advances in blood collection and processing technology to the marketplace.

Before CBER moves further ahead with this duplicative Device Action Plan, MDMA hopes that CBER and the FDA will step back and consider this common-sense idea we have advanced for your consideration. Not to do so would suggest that there are more issues in play here than simply the safety of the nation's blood supply.

Very sincerely yours,



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